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# Supreme Court of the United States

TOMMY G. THOMPSON,
SECRETARY OF HEALTH AND HUMAN SERVICES, *et al.*,
*Petitioners*,

v.

WESTERN STATES MEDICAL CENTER, *et al.*,
*Respondents*.

**On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit**

## *AMICI CURIAE* BRIEF OF JULIAN M. WHITAKER, M.D.; AMERICAN ASSOCIATION FOR HEALTH FREEDOM; DURK PEARSON; SANDY SHAW; PURE ENCAPSULATIONS, INC.; WELLNESS LIFESTYLES, INC. D/B/A AMERICAN LONGEVITY; HERO NUTRITIONALS, INC.; LIFE SERVICES SUPPLEMENTS, INC.; LIFE ENHANCEMENT PRODUCTS, INC.; AND LIFE EXTENSION FOUNDATION, SUPPORTING RESPONDENTS

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## INTEREST OF THE *AMICI CURIAE* [1]

***Julian M. Whitaker, M.D.*** is a physician licensed to practice medicine in California and Washington. Dr. Whitaker prescribes compounded drugs for special needs patients. The petitioners prohibit advertising of compounded drug availability and price. Dr. Whitaker relies on that information to obtain for those patients competitively priced compounded drugs as efficiently as possible. He is therefore adversely affected, as are his patients, by the petitioners' advertising ban.

***American Association for Health Freedom ("AAHF")*** is a Virginia non-profit corporation with over 500 physician, pharmacist, chiropractor and other health care practitioner members. AAHF endeavors to protect consumer access to preventive therapies and the right of health care providers to offer those therapies. AAHF's 240 physician members, including its nine physician board members, rely on the compounding services of pharmacists from across the nation. The drug price advertising the petitioners prohibit is precisely the advertising those members need most to provide their special needs patients competitively priced compounded drugs as efficiently as possible. Thus, AAHF's physician board members and physician members are adversely affected, as are their patients, by the petitioners' advertising ban.

***Durk Pearson; Sandy Shaw; Pure Encapsulations, Inc.; Wellness Lifestyles, Inc. d/b/a American Longevity; Hero Nutritionals, Inc.; Life Enhancement Products, Inc.; Life***

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[1] Counsel of record for the *amici curiae* authored this brief in whole. The *amici curiae* paid all costs associated with the preparation and submission of the brief with the exception of a monetary contribution made by Coastal Georgia Health Institute, Inc., 158 Scranton Connector Blvd., Brunswick, GA 31525. The *amici* have received the written consent for the filing of this brief from counsel to the petitioners and the respondents. Those letters have been filed with the Clerk of the Court.

***Extension Foundation; and Life Services Supplements, Inc.*** design, license and sell dietary supplements. As such, they are regulatees of the Food and Drug Administration (FDA). Their products labeling and advertising is directly (in the case of labeling) and indirectly (in the case of advertising) regulated by the FDA. The blanket speech ban here in issue, administered by the FDA, is substantively indistinguishable from the blanket bans imposed on these amici by FDA to prevent the communication of truthful dietary supplement health claims. *See Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999); *reh'g denied en banc*, 172 F.3d 72 (D.C.Cir. 1999)(hereinafter "*Pearson* I"); *Pearson v. Shalala*, 130 F. Supp.2d 105 (D.D.C. 2001) (hereinafter "*Pearson* II"); *Pearson v. Thompson*, 141 F. Supp.2d 105 (D.D.C. 2001) (hereinafter "*Pearson* III") (declaring such bans unconstitutional under the First Amendment). The legal validity of FDA blanket speech bans will likely be affected by this Court's First Amendment determination on the blanket ban here in issue. These amici thus have a keen interest in the outcome of the case.

## SUMMARY OF ARGUMENT

Upholding the decision below protects the First Amendment presumption favoring disclosure of truthful, nonmisleading health information over its suppression. It reaffirms the principles first articulated in *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council*, 425 U.S. 748 (1976), that weigh heavily against blanket bans on drug advertising.

In *Virginia State Board of Pharmacy* this Court held drug price information protected from a blanket advertising ban, reasoning that communication on the availability of the X prescription drug at the Y price was indispensable to consumers (indeed, was potentially more important to them than the day's most urgent political debate). *Id.* at 763. Here again the Court confronts a blanket ban on drug



advertising. That ban deprives physicians, including those among the amici, of information they need to locate competitively priced compounded drugs efficiently.

Drug compounding (the state regulated and licensed practice of manipulating drug content, delivery method, and dose to treat special needs patients) occurs on a case by case basis and is performed under state law either by individual physicians directly or by pharmacists pursuant to an individual physician's prescription. By contrast, drug manufacturing (the federally regulated production of standardized and FDA pre-approved drugs) occurs in mass, pre-set quantities and delivery forms for distribution to licensed drug retailers and licensed practitioners nationwide. Drug compounding when performed under state law is thus part of a physician's practice of medicine, a practice heavily regulated by the states. When a drug is prescribed by physicians for an unapproved use (i.e., for a use not evaluated by the FDA for safety or efficacy)—a practice especially common among oncologists and pediatricians—or is manipulated by or at the behest of a physician to satisfy the treatment needs of a specific patient, that is a "practice of medicine" regulated by the states. The "practice of medicine" is expressly exempt from federal regulation under the Food Drug and Cosmetic Act (FDCA). *See* 21 U.S.C. § 360(g)(2) (exempting "practitioners licensed by law to prescribe or administer drugs or devices and who manufacture, prepare, propagate, or compound, or process drugs or devices solely for use in the course of their professional practice" from the FDCA drug registration and inspection provisions); *see also* 21 U.S.C. § 374(a)(2)(A);(B); *Chaney v. Heckler*, 718 F.2d 1174, 1180 (D.C. Cir. 1983). The petitioners thus err when they argue to the Court that prior to the adoption of the FDA Modernization Act, Pub. L. No. 105-115, 111 Stat. 2296 (1997) (FDAMA), there existed no statutory basis for exempting compounded drugs from the FDCA's pre-market approval provisions.

But even were the drug pre-market approval provisions deemed applicable to patient specific compounded drugs (as the petitioners presume they are), it is not true that the FDA, pre-FDAMA, deemed itself incapable of regulating interstate traffic in compounded drugs. To the contrary, FDA has previously assumed that the FDCA's drug manufacturing and distribution provisions, 21 U.S.C. § 351; 355 (2001), left unchallenged in this litigation, grant FDA authority to limit the amount of compounded drugs entering interstate commerce. FDA has also assumed that those sections of the FDCA grant it authority to limit the kinds of substances that may be shipped interstate for use in compounding. *See e.g.*, FDA, *Compliance Policy Guides* (hereinafter, "*CPG*") 7132.16 Chap. 4 § 460.200 (1992) (revoked by FDA following passage of FDAMA). Thus, without the FDAMA sections here in issue (and without need for resort to speech restrictions), the petitioners have limited the mass interstate distribution of compounded drugs and substances for use in compounded drugs.

To be sure, it is possible to limit the amount and kind of compounded drugs in interstate commerce without imposing a blanket ban on advertising of specific compounded drugs and drug prices. The petitioners presume, however, that the power to regulate commercial activity carries with it a "lesser" included power to regulate speech concerning that activity. That underlying premise of the petitioners' argument is substantively indistinguishable from a false syllogism rejected by this Court in 1996. The view that the power to regulate a commercial activity includes within it the power to regulate speech concerning that activity, the so-called "greater-includes-the-lesser" syllogism, is, post *44 Liquormart v. Rhode Island*, 517 U.S. 484, 510-513 (1996), not good law.

The petitioners insist that they must ban compounded drug advertising to protect patient health and safety, but that argument too is lacking in persuasive force because health and safety regulation of pharmacy and physician com-



pounding has long been a province of the states. For decades hospitals, physicians, and pharmacists have engaged in compounding under extensive state regulation. Contrary to the petitioners' argument, that state system has had an outstanding safety record. It has been patients' first line of protection since the advent of modern pharmacy compounding in the late 1960's. There is no basis, and certainly no record evidence, to question the adequacy or effectiveness of state health and safety regulation of pharmacy and physician compounding.

The Congress of the United States and the FDA have recognized that regulation of compounding, like regulation of medical and pharmacy practice, is a matter of state concern. The FDAMA exemption afforded compounded drugs from the new drug approval provisions of the FDCA is but one of several statutory and regulatory exceptions to the general rule requiring federal pre-market drug approval. Those exceptions (such as for the practice of medicine and pharmacy, including compounding; for unapproved uses of FDA approved drugs; for personal use importation of unapproved drugs from outside the United States; and for experimental use of unapproved drugs) provide physicians the flexibility they must have to treat patients for whom approved drugs are either inappropriate, ineffective, or dangerous.

Here, as in *Rubin v. Coors Brewing Company*, 514 U.S. 476 (1995), the Government's justification for its speech ban rests on an irrational regulatory scheme. On the one hand, the Government permits pharmacy advertising of the existence of compounding services, arguing that it can allow that advertising without fear of increased demand for compounded drugs. On the other, the Government forbids pharmacy advertising of the existence of specific compounded drugs at specific prices, arguing that it cannot allow that advertising without fear of increased demand for compounded drugs. The argument apparently presumes that physicians seeking compounded drugs will be less apt to find

those drugs if they are only informed of the places that sell them rather than of the availability, classes, types, and prices of compounded drugs sold. That argument is counterintuitive and wholly speculative backed by not one shred of record evidence despite its illogic. This Court has repeatedly rejected such speculative argument as insufficient to satisfy the Government's high First Amendment burden. *See Coors*, 514 U.S. at 487-489; *Edenfield v. Fane*, 507 U.S. 761, 770-771 (1993); *Ibanez v. Florida Department of Business and Professional Regulation*, 521 U.S. 136, 143 (1994); *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*, 471 U.S. 626, 648-649 (1985). Logically, while less information may make the cost of obtaining a compounded drug higher than would otherwise be the case, it will likely not dissuade a physician intent on obtaining a compounded drug for a patient in need if that physician receives information on the existence and location of compounding pharmacies. Thus, the Government's position, dependent on speech suppression, provides at best only remote, indirect, and ineffective support, if any, for the Government's goal of keeping the demand for compounded drugs at some unarticulated lower than free market level.

In the present case the petitioners have not established that the FDAMA speech ban on compounded drug advertising (reaching even the phrase, "I will sell you the X compounded prescription drug at the Y price") directly and materially advances their goal of reducing to some unspecified below market level the amount of compounded drugs. They have not established the rationality of a regulatory scheme that allows advertising of compounding services but not of specific compounded drugs. They have not established the absence of numerous and obvious less restrictive alternatives (such as limits on the drugs available for compounding and on the amount of compounded drugs distributed interstate). Thus, having failed the direct advancement and means-ends tailoring prongs of *Central Hudson Gas & Electric v. Public*



*Service Commission of New York*, 447 U.S. 557 (1980) (as modified by its progeny), the Government's speech ban is unconstitutional. This Court should therefore uphold the decision of the United States Court of Appeals for the Ninth Circuit invalidating the speech ban.

This case is not unique. The lower federal courts have repeatedly condemned FDA blanket speech bans on truthful health information to no avail; FDA's acts of suppression continue largely unabated. *See Pearson I*, 164 F.3d 650; *Pearson II*, 130 F. Supp.2d 105; *Pearson III*, 141 F. Supp.2d 105; *see also* S.Rep. No. 105-43, at 50 (1997). The FDAMA blanket ban is thus part of a common, redundant approach favored by petitioners, an approach they employ undeterred by constitutional mandates in specific cases to the contrary. The precedential import and impact of the present case is thus profound and will necessarily be viewed as expressing the Court's willingness to condone similar FDA violations in future. The amici therefore urge the Court when resolving the current controversy to make clear that would-be health information speech police must abide by the same high First Amendment standard this Court expects of other would-be regulators of commercial speech, emphasizing that FDA regulators cannot shirk their constitutional duty to satisfy the First Amendment standard and must, consistent with that standard, favor disclosure of health information as the rule (relegating suppression to the status of a rare exception).

## ARGUMENT

### I. HEALTH AND SAFETY REGULATION OF COMPOUNDING HAS LONG BEEN A STATE PROVINCE

The preparation of patient-specific formulations by pharmacies and physicians (compounding [2]) has been a part of

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[2] Compounding has been succinctly defined as a process by which a pharmacist "combines, mixes, or alters ingredients to create a certain

medical and pharmacy practice for thousands of years. In modern times, compounded preparations are essential for special needs patients, such as children and the elderly who may have difficulty swallowing patented drugs in their commercially available dosage forms; hospitalized patients who need parenteral nutrition for extended recuperative stays; and cancer patients who need compounded chemotherapy cocktails. It is thus no exaggeration to say that longevity and pain relief are in no small measure due to the ability of physicians, pharmacists, and veterinarians to compound medications expeditiously for their special needs patients.

### A. The Historic and Indispensable Role of Compounding

Compounding is a practice as old as the first preparers of remedies for the first recorded civilizations.[3] Ancient Babylonian-Assyrian medicine included a class of "preparers of remedies" whose functions included compounding.[4] Compounding was practiced by apothecaries in ancient Egypt as recorded in the Ebers Papyrus circa 1500 B.C.[5] The scriptures refer to the art of the apothecary and to compounding: "And thou shalt make it an oil of holy ointment, an ointment compound after the art of the apothecary: It shall be an holy anointing oil." Exodus 30:25. *See also* Loyd V. Allen, Jr., Ph.D., *The Art, Science, and Technology of Pharmaceutical Compounding* xi (1998).

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medication for a patient." *Professionals & Patients for Customized Care v. Shalala*, 847 F. Supp. 1359, 1361 (S.D. Tex. 1994), *aff'd*, 56 F.3d 592 (5th Cir. 1995).

[3] Loyd V. Allen, Jr., Ph.D., *The Art, Science, and Technology of Pharmaceutical Compounding* xi (1998)

[4] Edward Kremers and George Urdang, *History of Pharmacy: A Guide and a Survey* 4-7 (1947).

[5] *See id.* at 387; *see also* Charles H. LaWall, *The Curious Lore of Drugs and Medicines* 11 (1927).



During the Norman period in England, the word "apothecary . . . designated anyone who kept a shop or store of such nonperishable commodities as spices, drugs, combits, and preserves." Harold B. Gill, Jr., *The Apothecary in Colonial Virginia* 1 (1972). From approximately 1300 to 1500, "the term [apothecary] was restricted to those who prepared and sold drugs," *Id.* at 1.[6] Until the late 1700's apothecaries who learned their skills through apprenticeship performed roles commonly associated with physicians. *See id.* On the eve of the nineteenth century, there first arose a professional distinction between druggists and apothecaries, on the one hand, and physicians, on the other. *See id.* Before that time, it was common for apothecaries to diagnose disease and dispense drugs. *See id.* at 8.

In June 1632, Parliament passed a law making it unlawful for apothecaries to sell drugs without a physician's prescription, but the law was honored more in the breach. *See id.* Parliament's passage of the Apothecaries' Act of 1815 caused a true separation between the medical and pharmaceutical professions in England. *See id.* at 15. From the 17th century until at least 1851, apothecaries in America performed the dual role of druggist and physician.[7] Modern

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[6] Even at this early date, concern arose among professionals for quality apothecaries and drugs, as evidenced by the words of English physician William Bulleyn who died in 1576:

> His place of dwelling must be cleanly, to please the senses withal. His garden must be at hand with plenty of herbes, seeds, and roots. He must have his mortars, stills, pots, filters, glasses, boxes, clean and sweete. He must have two places in his shop, one must be clean for physic, and [the other a ] base place for chirurgic stuff. He is neither to [increase nor] diminish the physician's prescriptions. He is neither to buy nor sell rotten drugs . . . .

*Id.* at 14.

[7] During his 1788 travels in America, Frenchman Jacques P. Brissot de Warville observed: "The greatest part of these physicians [at Philadelphia] are, at the same time, apothecaries. They continue to unite these two

professional pharmacies first appeared in the United States in 1851.[8] It was not until the second World War, however, that consumers came to rely primarily on physicians, rather than apothecaries, for medical advice.[9] Moreover, patent medicines were quite scarce in America before the end of World War II. Consequently, local plants, such as Indian hemp, papoose root, Indian mallow, and snake root were commonly compounded by apothecaries. Gill, *supra*, at 40.

Modern regulation of pharmacy as a distinct profession began with model state laws initially introduced at the Chicago meeting of the American Pharmaceutical Association in 1869. *See* Kremers, *supra*, at 199. By 1909 all then extant states of the United States had adopted the model laws for the regulation of pharmacy. *See id.*

Despite the rise of mass manufactured drugs, compounding has remained an indispensable tool in modern medical and pharmaceutical practice.[10] In modern times, compounding permits physicians and veterinarians to respond to a wide variety of patient specific needs that cannot be accommodated, or cannot be accommodated adequately, with mass

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sciences out of respect to the people, who wish that the man who orders the medicine should likewise prepare it." Gill, *supra*,. at 28.

[8] Kremers et al, *supra*, at 293.

[9] ". . .[A]t least until World War II, apothecaries, or druggists, were often the first to be called upon for medical advice." John Duffy, *From Humors to Medical Science: A History of American Medicine* 7-8 (1993). *See also* LaWall, *supra*, at 11.

[10] Loyd V. Allen, Jr., Ph.D. has explained the basic distinction between "manufacturing" and "compounding:" "In general, compounding differs from manufacturing in that compounding involves a specific practitioner-patient-pharmacist relationship, the preparation of a relatively small quantity of medication, and different conditions of sale (i.e., specific prescription orders)." *The Art, Science, and Technology of Pharmaceutical Compounding*, *supra*, at 1.



manufactured drugs.[11] Compounding occurs routinely in hospitals, physicians' offices, veterinary clinics, and pharmacies. In 1995, compounded prescriptions represented approximately 11% of all prescriptions dispensed.[12] Anyone hospitalized for more than a day is almost always the beneficial recipient of compounded drugs. "In hospitals, compounding has always been a part of pharmacy practice; intravenous admixture programs were brought into hospital pharmacy departments in the 1960s and 1970s and many pediatric formulations are prepared routinely." Loyd V. Allen, Jr., Ph.D., *Allen's Compounded Formulations: The U.S. Pharmacist Collection, 1995-1998* VII (1997). The ubiquitous "IV" is usually a compounded solution prepared to satisfy the particular needs of the hospitalized patient.

Examples of compounded products dispensed every day by health care professionals include total parenteral nutrition solutions; intrathecal solutions for pain management (such as morphine solutions); most intravenous admixtures; many antibiotic preparations for ambulatory care; and most oncology preparations. *See generally*, *Compounding Parenteral Nutrition Solutions*, 2 International Journal of Pharmaceutical Compounding 5 (1998); *Compounding for Pain Management*, 2 International Journal of Pharmaceutical Compounding 2 (1998); *Compounding for Pain Management*, 4 International Journal of Pharmaceutical Compounding 1 (2000); *Compounding for a Diverse Ambulatory Patient Base*, 1 International Journal of Pharmaceutical Compounding 6 (1997); *Compounding for Hospice and Cancer Patients*,

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[11] *See The Art, Science, and Technology of Pharmaceutical Compounding*, *supra*, at 1: "Compounding is . . . essential to the provision of health care. Compounding can be as simple as the addition of a liquid to a manufactured drug powder, or as complex as the preparation of a multicomponent parenteral nutrition solution."

[12] *The Art, Science, and Technology of Pharmaceutical Compounding*, *supra*, at xii.

4 International Journal of Pharmaceutical Compounding 4 (2000). Pediatric medications are not generally available in an easy-to-swallow form; consequently pharmacists frequently make liquids for oral consumption from commercially available tablets/capsules. *See generally, Compounding for Pediatric Patients*, 5 International Journal of Pharmaceutical Compounding 1 (2001). Because those drugs often have relatively short shelf lives when put into solution, they must be compounded by the pharmacist. Geriatric medications for the elderly who have difficulty swallowing are also frequently compounded. *See generally, Exploring Compounding Options for Geriatric Patients*, 1 International Journal of Pharmaceutical Compounding 3 (1997). The need to vary dosage forms and to eliminate preservatives or allergy-producing excipients may lead a physician or pharmacist to cause a pharmaceutical product to undergo compounding before it is ingested or administered to a patient.[13]

Through compounding, pharmacists, physicians, and veterinarians prepare solutions, suspensions, topicals, and suppositories that provide alternative routes of administration sometimes necessary in the treatment of particular patients. They are also able to prepare select dosage forms from bulk drug ingredients. Compounding is required to prepare radioactive isotopes and cassettes, syringes, and other devices for drug administration in the home setting. *See id.* at xv-xvi.

There is now near universal scientific recognition of the need for compounding in the provision of patient care. In

[13] *See The Art, Science, and Technology of Pharmaceutical Compounding, supra*, at xii: "Complete pharmaceutical care must involve the dosage form, which might necessitate compounding a patient-specific form not available commercially; possibly the preparation of a product without a preservative or a specific allergy-producing excipient that must be removed from the formulation."



1990, the U.S. Pharmacopoeial Convention appointed a Pharmacy Compounding Practices Expert Advisory Panel to prepare a chapter on compounding for the USP and to prepare monographs on compounded products. The chapter on "Pharmacy Compounding Practices" appeared in 1996 and the first compounding monographs appeared in 1998. *See, Allen's Compounded Formulations, supra*, at 2; *see generally* United States Pharmacopoeial Convention, Inc., *United States Pharmacopoeia XXV/ National Formulary XX* (2002).

Far from constituting a health threat, compounding under state regulation is an indispensable tool in the treatment of disease and the alleviation of pain. Its modern use is a professional practice under the ever-watchful eye of state boards of medicine and pharmacy.[14]

### B. Modern State Regulation of Compounding

Every state extensively regulates pharmacy practice, including compounding.[15] Compounding is not regulated

[14] In its first decision concerning price advertising by pharmacists, this Court recognized the high degree of professionalism associated with a state licensed pharmacy practice, writing:

> [T]he practice is subject to extensive regulation aimed at preserving high professional standards. . . . . The Board is broadly charged by statute with various responsibilities, including the "[m]aintenance of the quality, quantity, integrity, safety and efficacy of drugs or devices distributed, dispensed or administered." . . . It also is to concern itself with "[ma]intaining the integrity of, and public confidence in, the profession and improving the delivery of quality pharmaceutical services to the citizens of Virginia."

*Virginia State Board of Pharmacy*, 425 U.S. at 750-751.

[15] *See* Ala. Code § 34-23-1 *et seq.* (2001); Alaska Stat. § 08.80.003 *et seq.* (2001); Ariz. Rev. Stat. § 32-1901 *et seq.* (2001); Ark. code ann. § 17-92-101 *et seq.* (2001); Cal. Business and Professions Code § 4000 *et seq.* (West 2001); Colo. Rev. Stat. Ann. § 12-22-101 *et seq.* (West 2001); Conn. Gen. Stat. Ann. § 20-570 *et seq.* (West 2001); Del. Code Ann. tit. 24 § 2501 *et seq.* (2001); D.C. Code Ann. § 3-1201.01 *et seq.* (2001); Fla. Stat. ch. 465.001 *et seq.* (2001); Ga. Code Ann. § 26-4-1 *et seq.* (2001);

separate from pharmacy but is accepted as an integral part of it. Consider, for example, Maryland's rather typical statutory definition of pharmacy practice:

> [To] "practice pharmacy" means to engage in any of the following activities:
>
> (i) Providing pharmaceutical care;
>
> (ii) Compounding, dispensing, or distributing prescription drugs or devices;
>
> (iii) Compounding or dispensing nonprescription drugs or devices;
>
> (iv) Monitoring prescriptions for prescription and nonprescription drugs or devices;

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Haw. Rev. Stat. Ann. § 461-1 *et seq.* (2001); Idaho Code § 54-1701 *et seq.* (2001); 225 Ill. Comp. Stat. Ann. 85/1 *et seq.* (West 2001); Ind. Code. Ann. § 25-26-13-1 *et seq.* (2001); Iowa Code Ann. § 155A.1 *et seq.* (West 2001); Kan. Stat. Ann. § 1625 *et seq.* (2000); Ky. Rev. Stat. Ann. § 315.002 *et seq.* (Michie 2001); La. Rev. Stat. Ann. § 1161 *et seq.* (West 2001); Me. Rev. Stat. Ann. tit. 32, § 13701 *et seq.* (West 2000); Md. Code Ann. Health Occupations § 12-101 *et seq.* (2001); Mass. Gen. Laws Ann. 112 § 24 *et seq.* (2001); Mich. Comp. Laws § 333.17701 *et seq.* (2001); Minn. Stat. § 151.01 *et seq.* (2001); Miss. Code Ann. § 73-21-69 *et seq.* (2001); Mo. Ann. Stat. § 338.010 *et seq.* (West 2001); Mont. Code Ann. § 37-7-101 *et seq.* (2001); Neb. Rev. Stat. § 71-1,142 *et seq.* (2001); Nev. Rev. Stat. Ann. § 639.001 *et seq.* (2001); N.H. Rev. Stat. Ann. § 318:1 *et seq.* (2001); N.J. Stat. Ann. § 45:14-11:11 *et seq.* (2001); N.M. Stat. Ann. § 61-11-2 *et seq.* (Michie 2001); N.Y. Educ. Law § 6800 *et seq.* (2001); N.C. Gen. stat. § 90-85.2 *et seq.* (2000); N.D. Cent. Code § 43-15-01 *et seq.* (2001); Ohio Rev. Code Ann. § 4729.01 *et seq.* (Anderson 2000); Okla. Stat. tit. 59, § 353 *et seq.* (2000); Or. Rev. Stat. § 689.005 *et seq.* (2000); Pa. Stat. Ann. tit. 63, § 390-1 *et seq.* (West 2001); R.I. Gen. Laws § 5-19-1 *et seq.* (2001); S.C. Code Ann. § 40-43-10 *et seq.* (West 2000); S.D. Codified Laws § 36-11-1 (Michie 2001); Tenn. Code Ann. § 63-10-301 *et seq.* (2001); Tex. Occ. Code Ann. § 551.001 *et seq.* (West 2001); Utah Code Ann. § 58-17a-101 *et seq.* (2001); Vt. Stat. Ann. tit. 26 § 2021 *et seq.* (2001); Va. Code Ann. § 54.1-3300 (Michie 2001); Wash. Rev. Code Ann. § 18.64.001 *et seq.* (2001); W. Va. Code § 30-5-1 *et seq.* (2001); Wis. Stat. Ann. § 450.01 *et seq.* (West 2001); Wyo. Stat. Ann. § 33-24-101 *et seq.* (2001).



> (v) Providing information, explanation, or recommendations to patients and health care practitioners about the safe and effective use of prescription or nonprescription drugs or devices; or
>
> (vi) Identifying and appraising problems concerning the use or monitoring of therapy with drugs or devices.

Md. Code Ann. Health Occupations § 12-101.

Pharmacists and physicians who compound and physicians who prescribe compounded drugs must adhere to generally recognized standards of care enforced by state boards of pharmacy and medicine.[16]

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[16] *See* (Pharmacists) Ala. Code § 34-23-2; Alaska Stat. §§ 08.80.003-08.80.005; Ariz. Rev. Stat. § 32-1904; Ark. code ann. § 17-92-205(a); Cal. Business and Professions Code § 4005; Colo. Rev. Stat. Ann. § 12-22-101; Conn. Gen. Stat. Ann. § 20-576; Del. Code Ann. tit. 24 § 2501; D.C. Code Ann. § 3-1204.08; Fla. Stat. ch. 465.002; Ga. Code Ann. § 26-4-3; Haw. Rev. Stat. Ann. § 461-1; Idaho Code § 54-1702; 225 Ill. Comp. Stat. Ann. 85/1; Ind. Code. Ann. § 25-26-13-1; Iowa Code Ann. § 155A.2; Kan. Stat. Ann. § 65-1627; Ky. Rev. Stat. Ann. § 315.002; La. Rev. Stat. Ann. § 1162; Me. Rev. Stat. Ann. tit. 32, §§ 13711, 13721, 13723; Md. Code Ann. Health Occupations § 12-205; Mass. Gen. Laws Ann. 112 § 24; Mich. Comp. Laws § 333.17722; Minn. Stat. § 151.01; Miss. Code Ann. § 73-21-83; Mo. Ann. Stat. § 338.140; Mont. Code Ann. §§ 37-7-101, 37-7-201; Neb. Rev. Stat. § 71-1,142.09; Nev. Rev. Stat. Ann. § 639.070; N.H. Rev. Stat. Ann. § 318:5-a; N.J. Stat. Ann. § 45:14-14:1,45:14-3; N.M. Stat. Ann. § 61-11-6; N.Y. Educ. Law § 6804; N.C. Gen. stat. §§ 90-85.2, 90-85.6; N.D. Cent. Code § 43-15-10; Ohio Rev. Code Ann. §§ 4729.02, 4729.04; Okla. Stat. tit. 59, §§ 353, 353.7; Or. Rev. Stat. §§ 689.025, 689.135; Pa. Stat. Ann. tit. 63, § 390-6; R.I. Gen. Laws § 5-19-6; S.C. Code Ann. § 40-43-60; S.D. Codified Laws §§ 36-11-1, 36-11-11; Tenn. Code Ann. § 63-10-501; Tex. Occ. Code Ann. § 554.002; Utah Code Ann. § 58-17a-201; Vt. Stat. Ann. tit. 26 § 2032; Va. Code Ann. § 54.1-3305; Wash. Rev. Code Ann. § 18.64.005; W. Va. Code § 30-5-2; Wis. Stat. Ann. § 450.02; Wyo. Stat. Ann. § 33-24-102. *See also* (Physicians) Ala. Code § 34-24-53; Alaska Stat. §§ 08.64.100, 08.64.101; Ariz. Rev. Stat. § 32-1403; Ark. code ann. § 17-95-303; Cal. Business and Professions Code § 2220; Colo. Rev. Stat.

## II. CONGRESSIONAL AND FDA RECOGNITION AND ACCEPTANCE OF STATE COMPOUNDING REGULATION

Almost sixty years before adoption of FDAMA, Congress chose to exempt from FDA drug registration and inspection pharmacies and physicians whose compounding practices complied with state laws governing those practices.[17] Congress also chose to exempt from FDCA misbranding provisions any drug dispensed by filling or refilling a valid prescription from a licensed physician.[18]

Before FDAMA, federal courts understood 21 U.S.C. § 360(g)(2) to create a "practice of medicine" exemption to the FDCA. *See Cowan v. United States,* 5 F. Supp.2d 1235,

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Ann. §§ 12-36-102, 12-36-104; Conn. Gen. Stat. Ann. § 20-8a; Del. Code Ann. tit. 24 §§ 1701, 1730; D.C. Code Ann. § 3-1202.03, 3-1204.08; Fla. Stat. ch. 458.307; Ga. Code Ann. § 43-34-21; Haw. Rev. Stat. Ann. § 453-5.1; Idaho Code § 54-1806; 225 Ill. Comp. Stat. Ann. §§ 60/8, 60/9; Ind. Code. Ann. § 25-22.5-2-7; Iowa Code Ann. § 148.2A; Kan. Stat. Ann. § 65-2812; Ky. Rev. Stat. Ann. § 311.565; La. Rev. Stat. Ann. § 1261; Me. Rev. Stat. Ann. tit. 32, § 3269; Md. Code Ann. Health Occupations § 12-101; Mass. Gen. Laws Ann. 112 § 2; Mich. Comp. Laws § 333.17021; Minn. Stat. § 147.001; Miss. Code Ann. §§ 73-25-3, 73-25-30; Mo. Ann. Stat. § 334.120; Mont. Code Ann. §§ 37-3-203, 37-3-101; Neb. Rev. Stat. § 71-111,71-1,104.06; Nev. Rev. Stat. Ann. §§ 630.003, 630.130; N.H. Rev. Stat. Ann. § 329:2; N.J. Stat. Ann. §§ 45:9-22.1, 45:9-22:18; N.M. Stat. Ann. §§ 61-6-10.8, 61-6-10.9; N.Y. Educ. Law §§ 6508, 6509; N.C. Gen. stat. § 90-2; N.D. Cent. Code § 43-17-07.1; Ohio Rev. Code Ann. § 4731.20; Okla. Stat. tit. 59, §§ 481, 509; Or. Rev. Stat. §§ 677.015, 677.265; Pa. Stat. Ann. tit. 63, §§ 422.3, 422.8; R.I. Gen. Laws § 5-37-1.3; S.C. Code Ann. § 40-47-20; S.D. Codified Laws § 36-4-29; Tenn. Code Ann. § 63-6-101; Tex. Occ. Code Ann. § 153.001; Utah Code Ann. § 58-67-201; Vt. Stat. Ann. tit. 26 § 1353; Va. Code Ann. § 54.1-2911; Wash. Rev. Code Ann. § 18.71.015; W. Va. Code §§ 30-3-1, 30-3-7; Wis. Stat. Ann. § 448.02; Wyo. Stat. Ann. § 33-26-202.

[17] 21 U.S.C. §§ 360(g)(1);(2); 374(a)(2)(A);(B).

[18] 21 U.S.C. § 353(b)(2).



1240-1241 (N.D. Okla. 1998); *United States v. Algon Chemical, Inc.*, 879 F.2d 1154 (3rd Cir. 1989); *Chaney,* 718 F.2d 1174. In *Chaney*, the D.C. Circuit explained the purpose of the exemption as follows:

> The better explanation for the practice-of-medicine exemption is that Congress did not want to interfere with physicians' treatment of their patients. New uses for drugs are often discovered after FDA approves the package inserts that explain a drug's approved uses. Congress would have created havoc in the practice of medicine had it required physicians to follow the expensive and time-consuming procedure of obtaining FDA approval before putting drugs to new uses. Thus Congress exempted the practice of medicine from the Act so as not to limit a physician's ability to treat his patients.

718 F.2d at 1180.

Prior to FDAMA, FDA had generally exercised enforcement discretion to avoid the prosecution of physicians and pharmacists whose compounding practices with unapproved drug substances did not introduce into interstate commerce harmful drug products. *See e.g., CPG* 7132.16. FDA did so recognizing that drug compounding, as opposed to drug manufacturing, was a legitimate practice when performed by licensed professionals under state law. In 1992 FDA adopted its *CPG* 7132.16 (rescinded in January of 1999 to implement the compounding provisions of FDAMA (*see* 64 Fed. Reg.1,207)). Another FDA *CPG* allows within certain limits the compounding of veterinary drugs. *See CPG* 7125.40 Chap. 6 § 608.400 (2001).

## III. COMPOUNDING IS BUT ONE OF SEVERAL EXEMPTIONS FROM THE FDCA'S DRUG APPROVAL PROCESS

The "practice-of-medicine" exemption, 21 U.S.C. § 360(g)(2) (exempting "practitioners licensed to prescribe or administer

drugs or devices and who manufacture, prepare, propagate, compound, or process drugs or devices" from the FDCA's registration and inspection requirements) (see also 21 U.S.C. § 374(a)(2)(A);(B)), like the FDAMA exemptions for pharmacy compounding, are not unique. By FDA policy, under certain circumstances unapproved drugs may be imported into the United States on the prescription of a physician. *See* FDA, *Regulation Procedures Manual* (hereinafter "*RPM*"), "Coverage of Personal Importation," Chapter 9, (August 1997). Moreover, FDA has long allowed unapproved uses of approved drugs. *See* Stuart L. Nightingale, M.D., *Use of Drugs for Unlabeled Indications*, FDA Perspective, 269 (September 1986). Further, unapproved drugs may be prepared for and administered by physicians in clinical trials authorized by FDA. 21 U.S.C.A. § 355(I); 21 C.F.R. § 312 (2001). Those caveats to the general rule have also been crafted in recognition of the professional status of physicians and pharmacists and their independent regulation by the states.

### A. The Statutory and Regulatory Exemptions from New Drug Approval

#### 1. *Personal Use Importation of Unapproved Drugs*

While it is generally illegal to import unapproved drugs, in response to a market that demands medical treatments lawful abroad but not domestically FDA has created a personal use importation policy. That policy permits unapproved drugs to be imported via personal baggage or mail shipment into the United States in personal-use quantities. *See generally, RPM, supra*, at Chap. 9.

#### 2. *Unapproved Uses of Approved Drugs*

Under 21 U.S.C. § 352, the FDA has no authority to regulate the practice of medicine or to restrict the manner in which a physician may use an FDA approved drug. Indeed,



Congress did not intend FDA to regulate the practice of medicine or to interfere with a physician's ability to treat patients. *See* S. Rep. No. 74-361, at 3 (1935); S. Rep. No. 74-646, at 1 (1935) (explaining that the enactment of the FDCA was not intended to permit FDA to interfere with medical practice as between the physician and patient); H.R. Rep. No. 74-2755, at 5 (1936); S.Rep. No. 87-1744, pt. 1; at 56 (1962). Case law also confirms that the FDCA does not grant FDA authority to prohibit a doctor from prescribing a lawful drug for a purpose not approved by FDA. *See Cowan*, 5 F. Supp. 2d at 1240-1241; *Algon Chemical*, 879 F. 2d at 1160-1163; *Chaney*, 718 F.2d at 1180, *rev'd on other grounds*, 470 U.S. 821(1985); *United States v. Evers*, 643 F.2d 1043, 1048 (5th Cir. 1981).

Moreover, FDA recognizes that unapproved uses of approved drugs may be appropriate and necessary, and may even represent important therapeutic innovations by physicians. *See Use of Drugs for Unlabeled Indications*, *supra*, at 269; Stuart L. Nightingale, M.D., *Unlabeled Uses of Approved Drugs*, 26 Drug Information Journal 141 (1992). FDA recognizes that accepted medical practice can include a use for a drug that is not included in its approved uses and that the unapproved use may be appropriate if based on controlled clinical trials or reliable medical opinion. *See Unlabeled Uses of Approved Drugs*, *supra*, at 142, *citing* 37 Fed. Reg. 16,503 (1972). Prescriptions for unapproved uses are common among pediatricians and oncologists. *See* American Academy of Pediatrics, *Few Prescription Drugs Labeled for Pediatric Use*, ¶ 1, 3 (visited Dec. 20, 2001) <http://www.babybag.com/articles/aap_drug.htm>; Daniel Troy, *The FDA and Off-Label Uses of Drugs and Devices*, ¶ 3 (visited Dec. 20, 2001) <http://www.mediainst.org/ digest/97fall/wlf.html>.

### 3. *Investigational Use of Drugs*

By statute and regulation, it has long been lawful for qualified physicians to use unapproved new drugs in clinical trials authorized by FDA. *See* 21 U.S.C.A. § 355(I); 21 C.F.R. § 312.

## B. FDA's Pre-FDAMA Limits on Substances Used in Compounding and on Interstate Distribution of Compounded Drugs

While the statutory exemption for the practice of medicine, 21 U.S.C. § 360(g)(2), would appear to entrust the states with the authority to regulate compounding, pre-FDAMA, FDA has construed its statutory authority to allow the imposition of federal limits on the amount of interstate distribution of compounded drugs and on the substances available for compounding. *See* 21 U.S.C. § 353 A(B)(1)(A). While the exercise of that pre-FDAMA authority is not before this Court, the petitioners lack credibility when they argue that they depend upon FDAMA's speech ban to limit the amount of compounded drugs in interstate commerce.

## C. The Non-Speech Provisions of the FDCA, Left Unchallenged in This Litigation, Have Been Construed to Permit Regulation of the Amount of Compounding and, To a Large Extent, the Availability of Substances for Compounding

Prior to FDAMA FDA issued a Compliance Policy Guide ("CPG"), "Manufacture, Distribution, and Promotion of Adulterated, Misbranded, or Unapproved New Drugs for Human Use by State Licensed Pharmacies," reflecting long-standing FDA policy on drug compounding articulated in related compliance policy guides, warning letters, and federal court decisions. *See CPG* 7132.16 (rescinded when the FDAMA provisions on drug compounding became effective, 64 Fed. Reg. 1,207). Under the CPG, FDA threatened



enforcement action against any pharmacy that compounded "in inordinate amounts . . . drug products that [were] commercially available in the marketplace" or were "essentially generic copies of commercially available, FDA-approved drug[s]." Moreover, FDA threatened enforcement action against any pharmacy that received, stored, or used drug substances not made in "FDA approved facility[ies]" or that distributed "inordinate amounts of compounded products out of state." *See* CP6 7132.16. Thus, through pre-FDAMA enforcement policy, FDA construed its statutory authority as authorizing it to limit the amount and kind of compounded drugs prepared and distributed in interstate commerce.

# IV. THE POWER TO REGULATE COMPOUNDING DOES NOT INCLUDE THE POWER TO REGULATE TRUTHFUL AND NONMISLEADING ADVERTISING

The petitioners' argument rests on an unmistakably clear premise that the power to regulate compounding, a commercial activity, includes within it the power to regulate advertising about that activity. In other words, the petitioners essentially reassert that the power to regulate a commercial activity is a power greater than that to regulate truthful and nonmisleading advertising about that activity. Yet that very "greater-includes-the-lesser" syllogism is a false one in our constitutional system. It guts the First Amendment presumption in favor of speech by rendering general regulatory power over commercial activity superior to constitutional protection for truthful speech. This Court has rejected the syllogism. *See, e.g., 44 Liquormart*, 517 U.S. at 510-513 ("Further consideration persuades us that the 'greater-includes-the-lesser' argument should be rejected for the . . . reason that it is inconsistent with both logic and well-settled doctrine"); *see also* Kurland, *Posadas de Puerto Rico v. Tourism Company: "'Twas Strange, 'Twas Passing Strange; 'Twas Pitiful, 'Twas Wondrous Pitiful,"* 1986 S.Ct.Rev. 1, 12-15.

Furthermore, the fact that in FDAMA the Government conditions receipt of a statutory exemption from the new drug approval requirements on relinquishment of the right to speak in no way lessens the First Amendment violation present. As the Court explained in *44 Liquormart*:

> Even though government is under no obligation to provide a person, or the public, a particular benefit, it does not follow that conferral of the benefit may be conditioned on the surrender of a constitutional right. *See, e.g., Frost & Frost Trucking Co. v. Railroad Comm'n of Cal.*, 271 U.S. 583, 594 (1926). In *Perry v. Sindermann*, 408 U.S. 593 (1972), relying on a host of cases applying that principle during the preceding quarter century, the Court explained that government "may not deny a benefit to a person on a basis that infringes his constitutionally protected interests—especially his interest in freedom of speech." *Id.*, at 597. That teaching clearly applies to state attempts to regulate commercial speech, as our cases striking down bans on truthful, nonmisleading speech by licensed professionals attest. *See, e.g., Bates v. State Bar of Ariz.*, 433 U.S. at 355; *Virginia Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748 (1976).

*Id.* at 513.

It is thus the case that the Government cannot overcome the strong First Amendment presumption in favor of truthful and nonmisleading commercial speech on the basis that its speech ban is limited to those who seek to engage in a commercial activity that it could lawfully limit.

Could it be that truthful compounded drug advertising is less deserving of First Amendment protection than other commercial speech? If there was any doubt about the intrinsic First Amendment value of truthful drug advertising, that doubt should have been put to rest in *Virginia State Board of Pharmacy,* 425 U.S. 748. The advertising ban at issue in *Virginia State Board* is in no respect materially



different from the advertising ban at issue here. Both forbid drug advertising, including communication of the following: "I will sell you the X prescription drug at the Y price." The *Virginia State Board* decision includes recognition that drug advertising carries with it profound importance for the price conscious consumer. That consumer could be a patient, as in *Virginia State Board*, or, as here, a physician searching for competitively priced compounded drugs for his special needs patient(s). The Court explained that drug advertising includes information essential for "the alleviation of physical pain or the enjoyment of basic necessities." *Id.* at 763-764. The free flow of that information is indispensable to the efficient and effective rendering of numerous private economic decisions whether made by patients directly or by physicians who must purchase compounded drugs expeditiously. *See id.* at 765. As in *Virginia State Board*, so too here, the advertising ban "does not directly affect" the alleged government interest "one way or the other." *Id.* at 769. Rather, "it affects" those interests "only through the reactions it is assumed people will have to the free flow of drug price information." *Id.* Yet, as this Court has stated repeatedly, governmental assumptions are not enough to overcome the First Amendment presumption in favor of disclosure over suppression. Indeed, the First Amendment has made disclosure the rule and suppression the exception, limited to circumstances of compelling justification, not to ones involving sheer speculation as to market reaction. *See* id at 770.

## V. THE GOVERNMENT'S JUSTIFICATION FOR BANNING ADVERTISING OF SPECIFIC COMPOUNDED DRUGS AND PRICES, BUT NOT OF THE AVAILABILITY OF COMPOUNDING SERVICES, LACKS RATIONALITY AND FAILS THE DIRECT AND MATERIAL ADVANCEMENT TEST

The petitioners argue that they must prohibit the advertising of specific compounded drugs and prices to encourage a reduction in the amount of compounded drugs and thereby reduce the risk that pharmacies will overstep a line they leave undefined between permitted "compounding" and prohibited "manufacturing." Nevertheless, the petitioners do allow advertising of the availability of compounding services by pharmacists.

The Government's position is self-defeating and irrational. It rests on the counterintuitive assumption that physicians intent on compounding will be dissuaded from doing so if their contacts with compounding pharmacies are based on general advertisements of the availability of pharmacy compounding services rather than on specific advertisements of the availability and price of pharmacy compounded drugs. In short, the Government asks the Court to accept on faith that allowance of the one kind of advertising and disallowance of the other will result in a reduction in overall compounding activity such that the undefined and thus elusive point at which drug "manufacturing" takes place will not be reached. But the Government's scheme is wholly illogical. Backed by nothing but counterintuitive supposition, it is irrational and, thus, incapable of justifying a blanket speech ban.

The Court rejected a similar irrational scheme in *Coors*, 514 U.S. 476. In *Coors*, the Government argued that a statutory prohibition on placement of alcohol content on beer labels and in beer advertising lessened "strength wars" by



reducing competition among brands based on the potency of beer. But the law in question allowed alcohol content labeling in states that required such labeling and limited its ban on alcohol content advertising to those states that affirmatively prohibited such advertising. The regulatory scheme thus failed to advance directly and materially the Government's interest due to the "overall irrationality of the Government's regulatory scheme." *Coors*, 514 U.S. at 488.

Likewise, here, if the Government's true aim is to prevent compounding from becoming "drug manufacturing," it makes no rational sense to prohibit pharmacies from advertising specific compounded drugs and prices but permit them to advertise the availability of compounding services. The regulatory scheme is self-defeating and irrational. Like the scheme in *Coors*, the one here cannot directly and materially advance the Government's asserted interest.

## VI. THERE ARE NUMEROUS AND OBVIOUS LESS RESTRICTIVE NON-SPEECH REGULATORY ALTERNATIVES TO THE GOVERNMENT'S SPEECH BAN

The petitioners lack credibility when they argue they need the FDAMA provisions stricken by the Ninth Circuit to reduce the amount of compounding to some unidentified below market level when prior to FDAMA FDA assumed power to limit the amount of compounded drugs in interstate commerce (and the substances available for compounding) based on its interpretation of the unamended FDCA. *See CPG* 7132.16. It is of course within the power of Congress to enact statutory provisions that limit the amount of compounded drugs in interstate commerce or that grant FDA authority to identify substances that may not be used in compounding, all without resort to a blanket ban on compounded drug advertising. Furthermore, the Government's concern that physicians may regard compounded drugs as

FDA approved if advertising is permitted can be resolved in the first instance by mandating use of a reasonable disclaimer to that effect. This Court has repeatedly held use of reasonable disclaimers constitutionally preferable to outright speech suppression. *See 44 Liquormart*, 517 U.S. at 499-500; *Ibanez*, 512 U.S. at 144-46; *Peel v. Attorney Registration & Disciplinary Comm'n of Illinois*, 496 U.S. 91, 110 (1990); *In re RMJ*, 455 U.S. 191, 203 (1982); *Central Hudson*, 447 U.S. at 571; *Bates*, 433 U.S. at 383-384. The lower courts have repeatedly ordered FDA to accept disclaimers as a less restrictive alternative to outright suppression of vital health information. *See Pearson* I, 164 F.3d 650; *Pearson* II, 130 F. Supp.2d 105; *Pearson* III, 141 F. Supp.2d 105; *see also Washington Legal Foundation v. Henney*, 56 F. Supp.2d 81, 87 (D.D.C. 1999) *rev'd on other grounds* 202 F.3d 331 (D.C.Cir. 2000). Finally, it is indeed true (albeit effectuation of this option would be harmful to Americans) that Congress could prohibit compounding altogether, again without violating the First Amendment (unless it could be shown that congressional action was motivated by a desire to suppress protected speech). The Court has regularly accepted the existence of numerous and obvious less restrictive alternatives to speech bans as evidence of an inadequate fit between the regulatory means chosen and the ends. That inadequate fit warrants invalidation of the FDAMA speech ban under the final prong of the *Central Hudson* test. *See Central Hudson*, 447 U.S. at 566; *see also 44 Liquormart*, 517 U.S. at 507-508; *Ibanez*, 512 U.S. at 143; *Edenfield*, 507 U.S. at 771-772.



## VII. SEVERAL LOWER FEDERAL COURT CASES REVEAL THE FDAMA SPEECH BAN TO BE PART OF A GENERAL FDA PATTERN OF SPEECH SUPPRESSIVE ACTIONS, ALL DIRECTLY INFLUENCED BY THE COURT'S RESOLUTION OF THE FIRST AMENDMENT ISSUE IN THIS CASE

The published cases in the lower federal courts concerning FDA regulation of speech reveal that the agency has repeatedly relied on blanket speech bans and has refused to abide by the requirements of the First Amendment. *See Pearson* I, 164 F.3d 650; *Pearson* II, 130 F. Supp.2d 105; *Pearson* III, 141 F. Supp.2d 105; *Washington Legal Foundation*, 56 F. Supp.2d 81. Indeed, the amici here include plaintiffs in litigation against the agency in three of those four First Amendment cases. Repeatedly, those decisions have faulted the FDA for suppressing vital health information on labels and in labeling. In one such case, the FDA suppressed a folic acid/neural tube defect claim that daily consumption of folic acid by women of childbearing age could reduce the incidence of neural tube defect births and deaths by as much as 50 percent. Congress found FDA's suppression of that claim contributed to many preventable neural tube defects. *See* S.Rep. No. 105-43, at 50 (1997) ("Undoubtedly, many children suffered from preventable neural tube defects as a result of FDA's delay in authorizing health claims"). Thus, there is an urgent need for this Court to make clear once again that adherence to the First Amendment is imperative and that neither Congress nor the FDA enjoy an exception from the Constitution's strictures when either presumes to regulate the communication of health information.

## CONCLUSION

For the foregoing reasons, the decision of the United States Court of Appeals for the Ninth Circuit should be affirmed.

Respectfully submitted,

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